

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-6, 11-12, and 45-77 are pending in the application, with claims 1-4, 45, 54, 64 and 74 being the independent claims. Claims 11 and 13-44 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. New claims 45-77 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

New claims 45-73 correspond to cancelled claims 14-22, 24-33, and 35-44. For example, new claims 45, 54, and 64 are redrafted forms of cancelled claims 14, 24, and 35, respectively, which have been rewritten to more clearly define Applicants' invention. Support for new claims 45-73 can be found throughout the specification as filed, *inter alia*, at page 26, line 27, to page 33, line 25; at page 34, lines 21-28; in Example 8, at pages 67-69; and in Figure 3D and Figure 13D.

New claims 74-77 are drawn to a method for identifying a compound having the potential to inhibit cytokinesis by determining the compound's ability to inhibit CYK-4 function by determining the compound's ability to inhibit self association of MKLP1 protein subfamily members. Support for new claims 74-77 can be found in the specification, *inter alia*, at page 32, lines 6-22; and at page 33, line 26, to page 34, line 27.

Applicants have also amended the specification at page 30, lines 19-22, to add a sequence identifier number after each the two listed examples of the MLKP1 family of proteins, CeM03D4.1b and HsMKLP1, both of which are currently identified by

GenBank accession numbers. The specification has been amended to insert SEQ ID NO:7 after the description of CeM03D4.1b, and SEQ ID NO:8 after the description of HsMKLP1. A substitute sequence listing, in the form of substitute Sequence Listing sheets and a substitute computer readable copy, is also submitted herewith containing the amino acid sequences for SEQ ID NO:7 and SEQ ID NO:8.

Pursuant to 37 C.F.R. § 1.825(a) and (b), Applicants assert that the substitute sequence listing sheets contain no new matter, and that the copy of the sequence listing in the computer readable form is the same as the substitute copy of the sequence listing submitted herewith.

SEQ ID NO: 7 and SEQ ID NO:8 represent the amino acid sequences of CeM03D4.1b and HsMKLP1, respectively, present as the cited GenBank accession numbers at the time of filing of the application. Accordingly, Applicants assert that the addition of these two amino acid sequences to the application's Sequence Listing, with insertion of sequence identifiers in the corresponding text of specification, does not constitute the addition of new matter because both sequences are inherent in the GenBank database accession numbers cited in the application as originally filed. Thus, support for SEQ ID NO:7 and SEQ ID NO:8 can be found inherently in the specification as originally filed.

Support for the addition of SEQ ID NO:7 and SEQ ID NO:8 can also be found in the printouts of the sequences as they existed in the GenBank database at the time of filing of the current application (June 18, 2001) and at the time of filing of the earliest priority application (EP 00 112 880.0, filed June 19, 2000). Applicants thus submit herewith the GenBank database printouts of the SEQ ID NO:7 and SEQ ID NO:8

sequences as they existed at the time of filing of the application, as Exhibit 1 (GenBank Accession Number U61955, protein ID 1397342 for CeM03D4.1b; submitted June 26, 1998) and Exhibit 2 (GenBank Accession Number X67155, SwissProt Q02241 for HsMKLP1; submitted January 19, 2000). Applicants also submit printouts from the GenBank database listing the revision histories for SEQ ID NO:7 (Exhibit 3 for GenBank Accession No. U61955) and SEQ ID NO:8 (Exhibit 4 for GenBank Accession No. X67155), indicating that the sequences submitted as Exhibits 1 and 2 are the sequences existing as the cited GenBank accession numbers at the time of filing of the application. Exhibits 1-4 are also cited and submitted in Applicants' First Supplemental Information Disclosure Statement submitted herewith.

These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

I. Rejection under 35 U.S.C. § 112, First Paragraph

The Examiner rejects claim 26 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. (Office Action, at paragraph IV, pages 2 and 3.)

Specifically, the Examiner alleges that the sequences of the MKLP1 subfamily members recited in claim 26 are essential to practice the claimed invention and that without the sequence information, one cannot practice the claimed invention (Office Action, at page 3, lines 6-7.) The Examiner further asserts that because the sequences cannot be incorporated by reference other than to issued US patents or US patent applications to be issued, and because, in the present case, the MKLP1 family member sequences recited in claim 26 are represented by GenBank database numbers, Applicant is required to amend the disclosure to include the material incorporated by reference (Office Action, at page 3, lines 8-13). The Examiner also states that the amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. (Office Action, at page 3, lines 13-16.)

To expedite prosecution and without acquiescing in the propriety of the rejection, Applicants have canceled claim 26. Applicants, however, have added new claim 56, which corresponds to cancelled claim 26 and which recites the same GenBank database accession numbers as cancelled claim 26. Applicants assert that the sequences of CeM03D4.1b and HsMKLP1 were known in the art and publicly available at the time of filing of the application through the GenBank database accession numbers disclosed in the specification. The GenBank database accession numbers are currently the same as at the time of filing of the application, and the sequences for these proteins are publicly available. Applicants therefore believe that the sequences for these proteins are not essential material and do not need to be incorporated into the application.

To expedite prosecution and without acquiescing in the propriety of the Examiner's rejection, however, Applicants have amended the current specification at page 30, lines 19-22, to add the sequence identifier number SEQ ID NO:7 after the description of CeM03D4.1b, and SEQ ID NO:8 after the description of HsMKLP1, the two examples of MLKP1 proteins listed in the specification, both of which are currently identified by GenBank accession numbers. Applicants also submit herewith a substitute sequence listing, in the form of substitute Sequence Listing sheets and a substitute computer readable copy, containing the amino acid sequences for SEQ ID NO:7 and SEQ ID NO:8, which represent the amino acid sequences of CeM03D4.1b and HsMKLP1, respectively, present in the cited GenBank accession numbers at the time of filing of the application.

Support for the addition of SEQ ID NOs. 7 and 8 can be found inherently in the application as originally filed, in the GenBank database accession numbers disclosed in the specification. As evidence that SEQ ID NO:7 and SEQ ID NO:8 represent the sequences for the CeM03D4.1b and HsMKLP1 proteins as they existed in the GenBank database at the time of filing of the application, Applicants submit herewith the GenBank database printouts for the CeM03D4.1b and HsMKLP1 protein sequences (SEQ ID NO:7 and SEQ ID NO:8, respectively) as they existed at the time of filing of the application, as Exhibit 1 (GenBank Accession Number U61955, protein ID 1397342 for CeM03D4.1b; submitted June 26, 1998) and Exhibit 2 (GenBank Accession Number X67155, SwissProt Q02241 for HsMKLP1; submitted January 19, 2000). Applicants also submit printouts from the GenBank database listing the revision histories for GenBank Accession No. U61955 (SEQ ID NO:7), as Exhibit 3, and GenBank Accession

No. X67155 (SEQ ID NO:8), as Exhibit 4, indicating that the protein sequences submitted in Exhibits 1 and 2 are the sequences existing at the time of filing of the application. Exhibits 1-4 are also cited and submitted in Applicants' First Supplemental Information Disclosure Statement submitted herewith application.

Applicants believe that the rejection of claim 26 under 35 U.S.C. § 112, first paragraph, has been overcome and respectfully request the Examiner to reconsider and withdraw this rejection.

II. Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejects claims 13-33 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. (Office Action, at paragraph V, pages 4-5.)

Specifically, the Examiner asserts that claims 13-33 are indefinite because the steps of the methods recited in claims 14 and 24 do not correlate to the preamble of the claims, which is identifying a compound capable of modulating cytokinesis, and because the essential steps in claims 13 and 23 are missing. (Office Action, at page 4, lines 12-13 and 16.) The Examiner also states that "it is unclear from the specification that there is a direct link between 'modulating cytokinesis' and 'modulating the ability of a CYK-4 GAP to promote GTP hydrolysis by a Rho family GTPase.'" (Office Action, at page 4, lines 13-15.)

To expedite prosecution and without acquiescing in the propriety of the rejection, Applicants have cancelled claims 13-33. Applicants have added new claims 45-63,

however, which are redrafted forms of cancelled claims 14-22 and 24-33. In particular, new claims 45 and 54 are redrafted forms of cancelled claims 14 and 24, respectively, which have been rewritten to more clearly define the claimed methods. For example, each of new claims 45 and 54, which correspond to cancelled claims 14 and 24, respectively, has also been redrafted to recite in its preamble a method for identifying a compound having the potential to inhibit cytokinesis (rather than a method for identifying a compound capable of modulating cytokinesis, as recited in cancelled claim 14) either by determining the compound's ability to inhibit the function of CYK-4 protein or fragment thereof to promote GTP hydrolysis by a Rho family GTPase (claim 45), or by determining the compound's ability to interfere with the function of CYK-4 protein or fragment thereof to bind to members of the MKLP1 subfamily of kinesin-like proteins (claim 54). New claims 45 and 54 have also been redrafted to more clearly define the recited steps and to specifically correlate the steps to the preamble of the claim.

With respect to the Examiner's statement that it is allegedly unclear from the specification that there is a "direct link between 'modulating cytokinesis' and 'modulating the ability of a CYK-4 GAP to promote GTP hydrolysis by a Rho family GTPase'" (Office Action, at page 4, lines 13-15), Applicants direct the Examiner's attention to the specification, at page 9, line 19, to page 15, line 2, and, in particular, at page 9, line 21, to page 10, line 2.

The Examiner also asserts that claims 13-15, 20-27, and 31-33 are allegedly indefinite because they recite "CYK-4" and "MLKP1," which the Examiner identifies as acronyms. (Office Action, at page 4, lines 18-19.)

To expedite prosecution and without acquiescing in the propriety of the rejection, Applicants have cancelled claims 13-15, 20-27, and 31-33. Applicants have added new claims 45-63, however, which are redrafted forms of the cancelled claims and which recite "CYK-4" or "MLKP1."

Applicants submit that the terms "CYK-4" and "MLKP1" do not render the claims indefinite because one of ordinary skill in the art could interpret the metes and bounds of the claims reciting these terms. As described in the specification at page 5, lines 11-25, "CYK-4" refers to a protein represented by the CYK-4 protein encoded by the *C. elegans* *cyk-4* gene, which derives its name from the *C. elegans* *cyk-4* locus. See Gönczy, P. *et al.*, *J. Cell Biol.* 144:927-946 (March 1999) and Jantsch-Plunger, V. *et al.*, *J. Cell Biol.* 149:1391-1404 (June 2000) (previously submitted as document nos. AT9 and AS13 in the Information Disclosure Statement submitted by Applicants on January 18, 2002). Sequences for the human and mouse CYK-4 proteins are provided in the specification as SEQ ID Nos. 2 and 4, respectively. The specification, in Example 2, at page 50, lines 1-22, also describes several domains of *C. elegans* CYK-4 that are shared by mouse, human, and *Drosophila* forms of CYK-4 and thus conserved among metazoans, indicating a general structure for CYK-4 protein: a conserved C-terminus containing a GTPase activating protein (GAP) domain; a C1 domain predicted to bind to diacylglycerol or phorbol esters; and an amino terminal coiled-coil domain that mediates the interaction of CYK-4 with ZEN-4/MKLP1 (see also page 14, line 18, to page 15, line 11; and page 31, lines 2-5). Figure 3D and Figure 13D also present schematic diagrams showing the similar domain structure of the *C. elegans* CYK-4 protein and its human analog, MgcRacGAP/human CYK-4 ("HsCYK-4"). Thus, one of skill in the art would

recognize the proteins represented by "CYK-4" and, consequently, could interpret the metes and bounds of a claim containing the term "CYK-4."

Similarly, one of ordinary skill in the art would recognize the proteins represented by the term "MKLP1 subfamily of proteins" recited in the claims at issue. "MKLP1" represents human mitotic kinesin-like protein 1, a member of the kinesin family of motor proteins, which is known to those of skill in the art by the term "MKLP1." See Lee *et al.*, *Mol. Cell. Biol.* 15:7143-7151 (1995), at page 7144, upper left column (previously cited and submitted as document AR16 in Applicants' Information Disclosure Statement, filed on January 18, 2002). Analysis of the conserved kinesin motor domain has been used to construct subfamilies of kinesin proteins, one of which is the MKLP1 subfamily, the members of which are known to those of skill in the art. See, for example, Raich, W.B., *et al.*, *Mol. Biol. Cell* 9:2037-2049 (1998); Powers, J., *et al.*, *Curr. Biol.* 8:1133-1136 (1998); and Adams, R.R. *et al.*, *Genes & Development* 12:1483-1494 (1998) (previously cited and submitted as document nos. AS21, AT20, and AR1 Applicants' January 18, 2002, Information Disclosure Statement). Thus, one of ordinary skill in the art would recognize the protein represented by "MKLP1 subfamily of proteins" and, as a consequence, could interpret the metes and bounds of a claim containing the term "MKLP1."

Thus, use of the terms "CYK-4" and/or "MKLP1" in the claims at issue therefore does not render the claims indefinite.

The Examiner further asserts that claims 23-33 are allegedly indefinite because each claim recites the term "interact" or "interaction," and that there is allegedly no unambiguous definition of the term such that one skilled in the art would know the metes

and bounds of the term. (Office Action, at page 5, lines 8-12.) The Examiner states that "[i]f the term 'interact' is intended to mean 'binding', the claims should be amended so." (Office Action, at page 5, lines 12-13.)

To expedite prosecution and without acquiescing in the propriety of the rejection, Applicants have cancelled claims 23-33. Applicants have added new claims 55-63, however, which are redrafted forms of the cancelled claims and which substitute the term "bind" or "binding" for the terms "interact" or "interaction," respectively.

The Examiner also asserts that claims 13, 23, and 25 are allegedly indefinite because claim 13 recites "a GAP domain" and claims 23 and 25 recite "a domain of said CYK-4 GTPase activating protein." The Examiner states that "[s]ince neither the art nor the specification defines the terms unambiguously, the claims are indefinite." (Office Action, at page 5, lines 14-17.)

To expedite prosecution and without acquiescing in the propriety of the rejection, Applicants have cancelled claims 13, 23, and 25. However, Applicants have added new claims 45, 54, and 55, which are redrafted forms of the cancelled claims 13, 23, and 25, respectively. Cancelled claim 13 recited "a GAP domain," while new claim 45 recites in step (ii) "wherein the CYK-4 protein or fragment thereof comprises a GTPase activating protein domain." The GTPase activating protein domain, which can also be referred to as a "GAP" domain (see and page 10, lines 7-10, of the specification at), is described in the specification at page 3, line 21, and at page 10, lines 7-10, and is illustrated in Figures 3D and 13D, contrary to the Examiner's assertion.

New claim 54 recites in (i) the phrase "comprises a domain that binds MKLP1 subfamily proteins," which is a redrafted form of the phrase "a domain of said CYK-4

GTPase activating protein that interacts with said member of the MKLP1 subfamily of proteins" in cancelled claim 23. Again, contrary to the Examiner's assertion, the specification describes the domain of CYK-4 that binds MKLP1 subfamily proteins. See, for example, the specification at page 31, lines 13-15; at page 32, lines 12-15; Figure 3D; and Example 8, at pages 67-69.

Lastly, new claim 55 recites "that comprises a domain that binds the CYK-4 protein," which is a redrafted form of the phrase "that comprises a domain that interacts with said CYK-4 GTPase activating protein" in cancelled claim 25. The latter phrase is not the same as the phrase "a domain of said CYK-4 GTPase activating protein that interacts with said member of the MKLP1 subfamily of proteins" referred to by the Examiner in cancelled claim 23. The phrase "that comprises a domain that binds the CYK-4 protein" in new claim 55 refers to the protein domain in MKLP1 that binds to CYK-4, which is described in the specification at page 6, lines 3-24; at page 15, lines 3-28; in Example 9, at pages 69-70 (MKLP1 is an ortholog of ZEN-4); and in Figure 14C.

The Examiner also asserts that claim 30 is allegedly indefinite because it recites "the N-terminal region containing amino acids 1-120" and, according to the Examiner, it is allegedly "unclear what is referred by the term." (Office Action, at page 5, lines 18-19.)

To expedite prosecution and without acquiescing in the propriety of the rejection, Applicants have cancelled claim 30. However, Applicants have added new claim 60, which is a redrafted form of the cancelled claim 30. New claim 60 recites "wherein the fragment of the CYK-4 protein comprises amino acid residues 1-120." Support for new claim 60 can be found in the specification in Example 8, pages 67-69, and in Figure 3D.

Applicants believe that the rejection of claims 13-33 under 35 U.S.C. § 112, second paragraph, has been overcome or rendered moot and respectfully request the Examiner to reconsider and withdraw the rejections.

III. Claim Objections

The Examiner objects to claims 13-16, 18, 20-26, 28, and 30-33 because they allegedly recite non-elected subject matter. (Office Action, at paragraph VI, pages 5-6.)

Specifically, the Examiner states that that "[w]hile claims that recite more than one elected species are permitted in an application during prosecution, those claims will remain objected to during prosecution." (Office Action, at page 6, line 5-7.) The Examiner states further that he "clarifies that the restriction to a single CYK-4 polypeptide in Paper No. 10 (April 17, 2003) is not a species election; rather it sets forth additional invention groups. In the instant case, Applicants elected human CYK-4 polypeptide." (Office Action, at page 6, line 7-10.)

Applicants request clarification regarding the Examiner's restriction to HsCYK-4 or murine CYK-4 and respectfully ask the Examiner to confirm that he is examining all generic linking claims reciting both human and murine CYK-4 as required under Section 809.03 of the Manual of Patent Examining Procedure (MPEP § 809.03 (May 2004)). Because, with the current amendment, claims 13-16, 18, 20-26, and 30-33 are cancelled, the generic claims at issue are new claims 45-63, *i.e.*, those claims elected for prosecution that recite CYK-4 generically and thus encompass both murine and human forms of the CYK-4 protein.

Although Examiner states in the pending Office Action that the claims have been restricted to either the human or murine form of CYK-4 in Paper No. 10 (April 17, 2003) and that this restriction was not an election of species, Applicants note that the Examiner has objected to the claims as containing non-elected matter, as if the restriction were an election of species. The Examiner has also not indicated on the face page of the pending Office Action that the claims are withdrawn.

According to MPEP § 809.03, if an application contains genus claims that link species ("linking claims") and the Examiner restricts the claims to individual species, the linking claims must be examined because the restriction requirement is subject to non-allowance of the linking claims. Section 809.03 also instructs the Examiner to specify in the restriction requirement which claims are considered to be linking by inserting Form Paragraph 8.12 when making restrictions that involve linking claims. Applicants note that in Paper No. 10, the Examiner did not mention that the claims being restricted to the human or murine form of the CYK-4 polypeptide (currently cancelled claims 7-10 and withdrawn claim 11) were linking claims and that the restriction requirement was subject to non-allowance of the linking claims.

Thus, Applicants respectfully request that the Examiner confirm that he is examining all generic linking claims elected for prosecution that recite CYK-4 generically and thus encompass both murine and human forms of the CYK-4 protein (currently new claims 45-63).


Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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It may be shorter because we only sequence overlapping sections once, or longer because we provide a small overlap between neighboring submissions.

This sequence was finished as follows unless otherwise noted: all regions were double stranded or sequenced with an alternate chemistry; an attempt was made to resolve all sequencing problems, such as compressions and repeats; all regions were covered by sequence from more than one subclone

NEIGHBORING COSMID INFORMATION:

The 5' cosmid is K08B4, 2300 bp overlap; 3' cosmid is H10D12, 1200 bp overlap. Actual start of this cosmid is at base position 1 of CELM03D4; actual end is at 37750 of CELM03D4

NOTES:

Coding sequences below are predicted from computer analysis, using the program Genefinder (P. Green and L. Hillier, ms in preparation).

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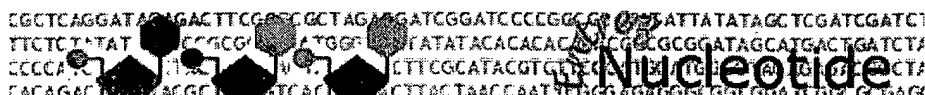
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2341 ctagcctccg atggggagat tgaaactaaa ctaattaagg gtgatattta taaaacaagg
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3241 attcctgcag cccgggggat ccactagtgc tagagcggcc gccaccgagg tggagctcca
3301 gcttttgttc cctttagtga ggggttaattt cgagcttggc gtaatcat

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GI	Version	Update Date	Status	I	II
3258581	1	Nov 12 2004 1:07 PM	Live		
3258581	1	Oct 25 2004 4:09 AM	Dead		
3258581	1	Aug 25 2004 4:37 AM	Dead		
3258581	1	Nov 19 2002 1:04 PM	Dead		
3258581	1	Aug 30 2002 3:10 PM	Dead		
3258581	1	Aug 28 2002 5:12 AM	Dead		
3258581	1	May 23 2002 11:02 AM	Dead		
3258581	1	Sep 21 2001 4:59 AM	Dead		
3258581	1	Jul 25 2001 4:56 AM	Dead		
3258581	1	Jun 26 1998 8:38 AM	Dead		
1397339	n/a	Jun 29 1996 1:00 AM	Dead		

Accession U61955.1 was first seen at NCBI on Jun 29 1996 1:00 AM

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GI	Version	Update Date	Status	I	II
6723674	2	Aug 27 2003 1:03 PM	Live		
6723674	2	Jan 20 2000 10:17 PM	Dead		
34671	1	Mar 9 1999 2:37 AM	Dead		
34671	1	May 29 1996 2:35 AM	Dead		
34671	1	May 23 1995 8:46 PM	Dead		
34671	1	Nov 30 1994 8:04 PM	Dead		
34671	1	Sep 3 1993 3:02 PM	Dead		
34671	1	Sep 1 1993 8:23 AM	Dead		
34671	1	Apr 21 1993 5:55 AM	Dead		

Accession X67155.2 was first seen at NCBI on Apr 21 1993 5:55 AM

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